

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Robert E. Grove, et al.

Application No.: 10/783,603

Group Art Unit: 3735

Filed: February 19, 2004

Examiner: David M. Shay

Title: EYE SAFE DERMATOLOGIC TREATMENT

APPARATUS AND METHOD

Customer No.: 54412

Date: 16 March 2008

Rule 132 Declaration of Dr. John F. Black

John F. Black declares and states as follows:


1. I received my Ph.D. from Nottingham University in 1987 and have worked since then designing lasers and therapeutic medical devices using laser devices. I am a named inventor on twelve patents and patent applications, and I have authored or co-authored over 25 articles, most of which relate to laser-based medical devices and treatments. As a consequence of my work, I am very familiar with the standards used by the U.S. Food and Drug Administration for determining laser safety, including particularly the standard set forth in 21 CFR 1040.10. When I use the term "eye safe" herein, I mean a device whose output satisfies the requirements of this standard for a Class I laser.
2. I have no financial interest in the outcome of this matter, nor do I have any prior relationship with SpectraGenics or any of the inventors of the above-named patent application except that I previously worked at Lumenis at the same time as Dr's Grove and Weckwerth and they occasionally visited the facility that I worked at. I am being compensated for my time at my normal consulting rate.
3. I have reviewed Dr. Michael Slatkine's patent application no. WO 03-049633 (the "'633"). The '633 application includes numerous misunderstandings of optical physics, and also includes designs which are improperly described as eye safe. I have determined that the '633 fails to teach even one instance of a device which is eye safe and effective for hair removal under the standard taught by the '633, although it does disclose designs which purport to be eye safe but are not.

4. It is well known among laser device designers that lasers represent a potentially serious eye hazard. It is also generally accepted that laser-based devices which emit sufficient fluence to remove hair operate at power levels far in excess of the FDA limits for Class I lasers. Thus, I was extremely surprised when I learned that Dr's. Grove, Weckwerth and Island had invented a laser device for hair removal which also met the Class I limits. Even with my many years of designing such devices, it is not obvious to me how such a combination was achieved.

5. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date: 3/16/08

John F. Black

A handwritten signature in black ink, appearing to read 'John F. Black', is written over a horizontal line.